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The LETOR

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Foreword

Consensus should consider experience of the past and current knowledge alike, and combine with trends predicted. Consensus should accept biomedical, technical, economic and cultural conditions.

Consensus if to be reached requires the term “appropriate” to be defined. Fascination with modern technology, new materials and digital techniques leads sometimes to over-fascination in P&O field where physiology is a major factor which can not be modified nor neglected. To achieve the goals and to avoid disillusion the “appropriate” means should be adopted rather than “the best” ones.

Consensus should develop the equilibrium between expectations of the clients, common beliefs, and interests of the equipment providers. Subjective self-assessment of an appliance by its user should not be overruled by data and/or categorization regarded as objective because they were established as standards, directives or recommendations by professionals with the use of advanced hardware and sophisticated methods. Without own practically verified experience no one should argue against well confirmed data analysis. Not listening to our patients leads to their frustration, and to our alienation.

Consensus if to be gained, last, and avoid situations like the Neurologic Control of Hybrid Orthoses symposium skipped in last moment from ISPO HK 2004 programme - must be based on revised facts.

Origin

Lower Extremity Telescopic Orthosis LETOR was developed at the Rehabilitation Center in Konstancin in cooperation with the Institute of Biocybernetics and Biomedical Engineering, the Polish Academy of Sciences [10]. Design proved to be appropriate in various environments and in different cultures.

Guidelines for the prefab modular splint were given by late Professor Marian Allan Weiss (1921-1981), founder of Konstancin 700-bed comprehensive rehab, a visionary and a pioneer in modern Prosthetics who in 1963 introduced in Copenhagen then a revolutionary concept of the Immediate Post-operative Fitting (IPOF). It was based on own experiments with combination of methods of a French prosthetist Berlemont and a German surgeon Dederich [5]. After 27 years of controversies and research the very first ISPO Consensus Conference was held in 1990 at NCTEPO, University of Strathclyde, in Glasgow. It contributed to shaping the contemporary Modular Prosthetics which evolved from IPOF concept.

Also Polish-born designers’ contribution to the development of advanced Orthotics is significant [10]; Wally Motloch by 1967 Reciprocating Gait Orthosis (RGO) and 1971 Parapodium, his former colleague Christopher Poplawski by 1989 ISO-Centric and 1994 BIO-Metric RGOs, and Professor Andrzej Olędzki by 1994 dynamic PIV parapodium with compensatory propulsion generated by shoulders musculature. LETOR belongs to that family of original, patented and effective products. However, in contemporary united world the origin of an idea is of lesser meaning than its application and the benefits thereof.
Background

Despite similarities, like common trends towards modularization, Orthotics if compared to Prosthetics is always a challenge [7]. To substitute lost function if one uses the space available after amputation is not easy, and even more difficult in spinal cord injury (SCI) with minimum construction and weight added to flaccid limb. In particular higher the SCI level is then less functions remain - in this situation splint must be longer and stronger, thus often heavier too. Biomechanical factors are offset by clinical ones. For instance if the orthotics of lower limb for infant patients should secure high stability in order to prevent deformity, orthotics for adults in contrast may feature certain “underbracing” therefore can be lighter in relation to body weight. Overbracing in general inhibits stimulation and delays progress of rehabilitation. Proprioception is our sense of self. Even after SCI some signaling from kinesthetic receptors in muscles, joints and tendons are still dealt with in the unconscious parts of the brain.

The energy cost of reciprocal gait after SCI is 6±8 times larger comparing to gait in norm (Gordon E. et al 1956) and that is why about 50% of SCI patients cease using prescribed and customized splints - even in Switzerland - not long after discharge from the hospital [2]. Can customized aids be perfect if those personalized by different practitioners for the same patient are not repeatable [6]? Mobility of severely disabled can be improved by a wheelchair but the activities in upright position should not be neglected - at least balance exercises are to be performed for inner organs functioning. While RGO is the most efficient orthotic system designed for the least fit walkers, while the Functional Electrical Stimulation (FES) is still a technique of a future rather than of today, while the researchers still search for a clue how to repair ruptured spinal cord - patients’ disappointment about their customized splints is common. In result there is a loss of public funds, there are cuts in further funding of functional SCI orthotics, and thus there is leaving for the patient not much alternative than living in a wheelchair.

Negligence of gait training create situation of higher risk due to hypokinesia which means abnormally decreased mobility, abnormally decreased motor function or activity, slow or diminished movement of body musculature. Hypokinesia may be associated with prolonged inactivity due to illness caused by pathology or trauma. After SCI hypokinesia often causes awkward health effects and gradually leads to urinary, digestive, vascular, pulmonary and metabolic disorders, as well as stress and depression.

Aim

The goal of LETOR project was to analyze a comprehensive spectrum of factors - from biomechanics, through medical and therapeutic conditions, to psychology and social aspects within the group of patients after SCI -- all that in order to design a relatively simple, lightweight, adjustable, clinically efficient, easy to don-doff, low-cost prefab KAFO for effective standing and reciprocal gait exercises.

Method

LETOR philosophy [7; 8] is based on reasons and details which together compose the aid to facilitate mobility. Next to the patient is a physiotherapist, a secondary user of this tool, and both benefit from:

- sufficient alignment - to fit the splint immediately on the patient;
- easy donning - externally over trousers and regular sport shoes;
- comfortable sitting - for necessary relax between periods of activity;
- active standing - with appropriate posture and stability to maintain body balance;
- enhanced walking - by built-in propulsive dynamic features compensating lost functions;
- controlled underbracing - to prevent blocking the process of neurological restoration;
- effective training - with the use of reduced knee orthotic support whenever it is permitted.

LETOR is prefabricated in one standard adult-size, adjustable, attached from rear, telescoping single upright splint, fixed in 3½ points, fastened over trousers, with sport shoes as elements of the system. Telescopic splint is designed to stabilize the paralyzed lower limbs in knee and ankle joints to provide necessary biomechanical conditions for standing and bipedal ambulation. On the applications record most patients are after SCI, however cases of polio, stroke, neoplasm, Wegener and Guillain-Barre were also successfully treated by improving patient’s body balance, mobility and independency [7; 9].
**Static**

*LETOR* is designed for safe and easy standing exercises. Rigid stirrup holds the foot from rear (Fig. 1) stabilizing ankle joint for better feeling of body balance in standing. For effective and safe, and yet for comfortable limb support, the cuffs feature angular self-alignment to match the individualized thigh and under-knee shapes. Widths are adjustable by bending the cuffs made of aluminum. Three velcro closures are applied plus optional above-knee strap. Quick lock (mark 3) is adopted for easier fixation of the telescopic set. Lock and the tube bolted clamp provide longitudinal and transverse alignments.

Displacement of instant center of rotation in biologic joints in vivo is load-dependent, thus uneasy to interface by external mechanical structure even with the use of polycentric hinges. Biomechanical compliance during limb flexion for comfortable sitting is achieved in *LETOR* in a most natural way: by flexing knee joint alone after thigh support is lowered down and relocated within the shank area.

Moderate forward slant of the splint column by 6° enforces patient lordotic posture. Standing in such a position can not be considered as appropriate in norm but after SCI enhanced lordosis is helpful in compensation of postural neuromuscular dysfunction -- provided there are no counter-indications.

**Kinematics**

*LETOR* is designed also for energy-efficient ambulation:
- efforts are spared by splint external donning-doffing;
- propulsive properties of stirrup, splint column and cuffs;
- semi-rigid splint column and spine ligaments function for energy storage.

Forefoot is left semi-elastic for easier ambulation. Heel posterior strait cut is aimed at correcting the limb rotation in hip joint thus setting the foot straight at each heel-on phase. Stirrup frontal slant cut facilitates lateral body shift after crossing the mid-stance phase for easy compensatory swing (Fig. 2). Reduction of spine/trunk flexibility by enforced lordotic posture not only facilitates the body balance in standing but also initiates compensatory swing. Due to tensions stored in the ligaments of spine the flaccid limb once released off the ground contact has a tendency to move forward, augmented by pendulum effect due to posterior splint attachment shifting the center of mass of the limb backward.
Dynamics

During walking in any stabilizing orthoses gravity-linked ground reactions are causing cyclic variable propulsive effects [7]. After heel-on the effect pushing patient forward through a thigh cuff appears. This propulsive force gets gradually reduced and zeroes in the mid-stance. While advancing the step further a counter-propulsive effect i.e. pulling body backward appears and gradually increases, then decreases again to zero in toe-off. Due to 6° forward slant of the splint and proportions of the heel the pushing effect in LETOR lasts over a limb angular sector ca. 3 times wider than in pull backward phase which is 3 times stronger instead. Hence, the overall gravity-linked influence is fairly balanced. Experienced user using upper-body musculature, supporting appliances and trunk inertia can reduce pulling force and augment the pushing effect by appropriate synchronization of pelvis rotation to gait rhythm and arms support. Direction of this pelvis rotation is natural for gait but timing is crucial and experience is needed to cut shorter the phases pulling backward and let springing energy to push.

Fig. 3. Cyclical variable PUSH-PULL forward/reverse effects from gravity-linked ground reactions
Underbracing

As little as possible orthotic support speeds-up recovery by reduction of inhibiting effects. Carefully selected shapes and materials create properties of LETOR at the first glance hidden as improvement due to the proprioception is unconscious. Due to limited elasticity of under-patella cuff and semi-rigid telescoping column the knee joint fixed by the LETOR splint is purposely set in a subtle 2±3° flexion, thus little play in knee are allowed in gait augmenting the kinesthetic signaling. Further, if functions return a gradual lowering of the thigh cuff allows the use of LETOR in a Reduced Support (RS) mode (Fig. 4) when gait restitution may be enhanced by smooth shift of the knee flexion-extension control from splint to reactivated muscles. This feature is particularly useful in incomplete SCI and in stroke.

Initial assessments

First sales (s) and clinical testing (t) of LETOR system were arranged in 1985-87 at following places:

1. STOCER Metropolitan Rehabilitation Center, Medical Academy - Konstancin, Poland (t)
2. Clinic and Department of Rehabilitation, Silesian Medical Academy - Repty, Poland (t)
3. Institute of Orthopedics and Rehabilitation, Medical Academy - Poznań, Poland (t)
4. County Hospital of Traumatic Surgery - Piekary Śląskie, Poland (t)
5. County Center of Orthopedic Services - Łódź, Poland (t)
6. County Orthopedic Supplies - Bytom, Poland (t)
7. EFOR Unit for Applied Orthotics - Jönköping, Sweden (s, t) / Svensk Handikappteknik AB (s)
8. DRI Dallas Rehabilitation Institute - Dallas TX, USA (s, t) / 3D Orthopedics Inc. (s, t)
10. Royal Perth Hospital - Perth, Western Australia (s)
11. CEBELOR Orthopaedic Centre - Bruxelles, Belgium (s, t)
12. Workmen Compensation Traumatic Hospital - Frankfurt, Germany (t) / GOTEPE mbH (s, t)
13. ORLAU Midland Centre for Spinal Injuries - Oswestry, England (t) / RTS Taylor Ltd (s)
14. NCTEPO University of Strathclyde - Glasgow, Scotland (s, t)
15. Royal National Orthopaedic Hospital - Stanmore, England (s)
16. Proteesissäätö - Helsinki, Finland (s)
17. LIC Espanola de Ortopedia S.A. - Madrid, Spain (s)
18. Rodolfo Rodriguez Benitez Tecnico Ortopedico - Las Palmas de Gran Canaria, Spain (s)
19. National Institute for Medical Rehabilitation - Budapest, Hungary (t)
20. Safdarjung Hospital - New Delhi, India (t)
22. modified telescopic orthosis sent to India for barefoot walking polio patients (t)
23. samples with Orthos polyurethane sandals sent by courtesy of CEBELOR to Central Africa (t).

Should be acknowledged that samples for national testing (pos. 1±6) have been sponsored by Polish Orthopedic Association ORTMED and few more were donated by our lab free of charge (pos. 19±23). With exception of 7 units involved (pos. 15±18; 21±23) opinions were kindly provided as expected. Obtained assessments were positive with exception of a statement received from Stoke Mandeville: [over a couple months] LETOR was tried there on one SCI patient and in that case the orthosis has been found inappropriate and next attempt planed was never reported. It seems that samples given for testing free apparently are being received by the recipients as the equipment of lesser usefulness.

Combined initial assessment of LETOR from other reporting facilities [7] complies with the conclusions published by American authors [4; 13]:

- useful in rehab centers for training and assessment;
- single upright stabilization in most cases sufficient;
- eliminates drawbacks of conventional orthoses;
- adjustment is fast, simple and convenient;
- easy to don/doff due to external fitting;
- relatively lightweight: ca. 1 kg per unit;
- helpful in body balancing and propulsion;
- may also be good for use at home -- when accepted.

![Fig. 4. Reduced Support](image-url)
After complains the early solution of telescoping set fixation by a tapping bolt has been re-designed: the butterfly bolt was rearranged into the clamp, and fiberglass rod was replaced by carbon fiber. Recently a quick lock is used to ease operation. Leather or nylon straps are considered as options.

**Indications:**
- paraplegia after trauma or pathology;
- lower limb flaccid dysfunction due to head injury (stroke), neurological disease, polio;
- quadriplegia - for active standing exercises only with assistance and the supporting handrail.

**Counter-indications:**
- stable contractures and/or significant spasticity - due to lack of snap lock in the knee joint;
- excessive weight, excessive height and /or excessive level of neuromuscular dysfunction;
- affected integrity of the knee joint.

**Variants**

At the beginning the *LETOR* was manufactured in 3 lengths and 3 stirrup widths. Upon sales analysis the manufacturer adopted policy to offer 1 standard size (suits ca. 90%) fitting the rest individually. Two child-size prototype sets have been made and fitted but follow-up opinions were not obtained. Single units for polio barefoot patients made in 1982 were sent to Africa and India and get lost there. The letter received from India stated that the person in charge for testing went abroad for studies.

**Follow-up**

In 1982 a SCI patient took on a discharge the telescopic prototypes that he was using for training at the Konstancin center. Early plans to retrieve the equipment were abandoned hence the very first definitive self-fitting was allowed to happen paving the way for legal fittings which followed later on.

Over 22 years once a week in average another patient was equipped with *LETOR* in Poland - country of 38 million, now member of the EU successfully switching to market economy. In 2001 funds were obtained from the National Committee for Scientific Research (KBN) and own-designed questionnaires were sent to 154 potential respondents - the *LETOR* users identified in supplier’s archive records [9]. One-page easy to tick comprehensive inquiry contained 143 questions grouped in 8 categories:

- dysfunction - health - influences
- mobility - activity - motivation
- equipments - self-assessments.

For reliability the anonymous procedure was guaranteed and the only reward offered was the access to the survey final report (this was selected by 72% respondents – those more active and with better motivation to be independent). Respondents were encouraged to provide most objective information and subjective, relative ratings. Data was obtained from 57 users - at that time accounting for ca. 5% of prescribed *LETOR* sets. Randomly traced group breakdown:

- gender: 12 female + 45 male
- age range: 16÷76 years; mean 37.4
- unreported genesis of disability: 10%
- trauma: 81% - SCI C6÷S1; mean Th11 (Fig. 5): 38% complete; in 3 sub-groups: 15x C6÷Th5; 11x Th6÷Th11; 25x Th12÷S1
- pathology: 9% - 2 cases neoplasm; 2 cases post-operative; 1 case SM; 1 case Wegener; 1 case vascular deficiency
- weight range: 50÷96 kg; mean 71.8
- height range: 153÷192 cm; mean 175.1
- accompanying health disorders: 1÷12 items (Fig. 7)
- period of *LETOR* use: 0.25÷15 years; mean 3.0 years.

![Fig. 5. SCI sub-groups](image)
In comparison to 50% abandoning rate quoted in literature [2] respondents have reported relatively high level of acceptance (Fig. 6): 75% telescopic splints in use, 5% given away due to the functional recovery, and 20% abandoned: 9% definitely while 11% unused devices were stored “just in case”. Respondents declared the following usage: for indoor activity 55%, for training 54%, outdoor 15%, while 9% users combined all modes, and 29% did most common mixture of exercises and indoor use.

Table presents the percentage breakdown in all sub-categories of opinions on splint external donning. Overall ratings are: no problem (NP) 56%; good compromise (GC) 23%; serious drawback (SD) 28%.

<table>
<thead>
<tr>
<th>SCI LEVEL</th>
<th>GC SD</th>
<th>NP GC SD</th>
<th>NP GC SD</th>
<th>NP GC SD</th>
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<tr>
<td>C6÷Th5</td>
<td>20 13</td>
<td>87 20 13</td>
<td>Th6÷Th11</td>
<td>64 27 27</td>
</tr>
<tr>
<td>GENDER female</td>
<td>33 17 25</td>
<td>male</td>
<td>62 24 29</td>
<td></td>
</tr>
<tr>
<td>AGE 16÷37</td>
<td>64 24 30</td>
<td>27 38 76</td>
<td>46 21 25</td>
<td></td>
</tr>
<tr>
<td>WEIGHT [kg]</td>
<td>50÷71 42</td>
<td>23 39</td>
<td>Th12÷S1</td>
<td>40 20 36</td>
</tr>
<tr>
<td>HEIGHT [cm]</td>
<td>153÷175 41</td>
<td>21 34</td>
<td>72÷96 71</td>
<td>23 25 17</td>
</tr>
<tr>
<td>PHYSICAL ACTIVITY low</td>
<td>45 9 18</td>
<td>medium</td>
<td>63 22 28</td>
<td>high 54 38 38</td>
</tr>
</tbody>
</table>

Characteristic is that those who higher than appearance rate functionality are: quadriplegics, younger, men, heavier, taller, and more intellectually active. Smarter veterans create more active elite (Fig. 8).

Data was obtained a.o. from patients who were using LETOR and other splinting too: double uprights and/or polypropylene shells and/or parapodium; most of respondents were using a wheelchair too.

Usefulness of mobility aids used (0÷100): wheelchair 90; LETOR 12; other splints 7; parapodium 7. Limb stability by the telescopic orthosis: sufficient 68%; too rigid 16%; too soft 5%; no answer 11%. One-size prefab alignment: easy 53%; little problem 35% (i.e. 88% OK); difficult 7%; no answer 5%. Durability: sufficient 56%; bad velcro 37%; bad rivet 19%; bad lock 14%; weak rod 11%; other 7%. Features: usefulness 68%; fabrication quality 58%; lightness 55%; esthetics 50%; no answer 19%. LETOR overall rating: very useful 16%; helpful 70%; sad necessity 12%; bad 0%; no answer 11%. Independence: functional self-care: full 28%; partial 72%; financial: full 19%, partial 70%, n.a. 11%. Mobility: sufficient 21%; poor 63%. Social environment: supportive 75%; neutral 21%; hostile 4%. Car availability: self driving 30%; in family 40%; occasional help 12%; complete lack of a car 12%. Engagement: family 78%; hobby 36%; sport 25%, work 19%; study 20%; politics 17%, farming 4%. Motivations for exercises: independence 61%; prevention 47%; duties 30%; no motivation 7%. Gait training influence on health: beneficial 67%; too early to say 12%; none 11%; no answer 12%.

Fig. 6. Use of prescribed LETOR in all INDOOR-TRAINING-OUTDOOR combinations (n=57)
Discussion

Despite answers were collected from ca. 1/3 of users inquired, the group of 57 respondents seems to be representative and data given seems to be reliable. Resulting 75% usage reported seems to reflect the reality corroborating information obtained directly from patients and physiotherapists.

Breakdown of accompanying health extra disorders can serve as another prove (Fig. 7) which confirms sad reality that inflammations of urinary tract is most common among paralyzed therefore less mobile veterans. Revealed disorders (mean 5.4 per person) are typical in SCI.

For data reliability respondents were encouraged to make assessments and give precise answers, but in difficulties were advised to leave a box empty. Silence is safer than false data. For instance as many as eight respondents got just unable to provide self-assessment of their level of activity (Fig. 8).

Due to normal distribution the data provided for this analysis seems to be representative yet. Interesting is question whether more active users get smarter, or smarter elite get physically more active. Both the influence directions are perhaps true.

**International interest**

*LETOR* was rated appropriate by clinicians and patients in Europe and USA, well received in India and China [10]. System fabricated since 1984 has been licensed to companies in Sweden and the USA.

Among orthotists *LETOR* prefab concept generates sometimes mixed feelings perhaps due to possible competition against own customized splints. This, if true, has to be regarded as the sign of natural progress of knowledge and technology. Example of IPOF evolved over ca. 30 years into contemporary *Modular Prosthetics*, may indicate that also future of the lower limb splinting is in modular orthotics.

This trend seems to be confirmed by interest in *LETOR* from international orthopedic companies:
- prototype with UV-hardened PALAPREG LHZ BASF parts by Svensk Handikappteknik AB 1986;
- prototype with carbon fiber parts by GOTEPE mbH successfully tried by polio patient 1986 [3];
- black version with nylon straps by 3D Orthopedics Inc. (DeRoyal) 1987-91 volume of 900 [1];
- prototype with s/steel telescope and ABS stirrup by RTS Taylor & Son Orthopedics Ltd 1989;
- sample purchased for evaluation by Otto Bock HealthCare GmbH after invited seminar 2001;
- adopted without authorization by PRO WALK GmbH and offered as "LEVATE" in ca. 2000-02;

Aluminum replaced in cuffs by fixed-form plastic reduced possibility to adjust the widths. Among all listed attempts the least modified version (USA) was fabricated in the highest volume: over 5 years 15 "TPO"-called splints were distributed each month as transient devices until company re-profiling.

**Applications**

In 2005 the total volume of official versions reached 3,450 units. After maturing period of 25 years the biggest scale of use of LETOR system in Poland contributed in getting experience and improving the comprehensive rehabilitation process provided on a regular basis with the following routines:
- a) assessments - device is useful in various states, and stages from active standing to reciprocal gait;
- b) training - with prefab splint flaccid limb can be stabilized immediately, at low cost with low weight;
- c) transient fitting - knee stability can be modified, usefulness can be tried before the order is made;
- d) definitive fitting - record of ca. 1,300 cases, mainly SCI, prescribed by doctor upon patient’ choice.

**Conclusions**

1. LETOR prefab orthosis due to its unique features constitute a valuable option among transient stabilizing lower limb orthotics for body balance exercises, gait training, and assessment (Fig. 9).

   ![Fig. 9. Scheme map of LETOR prime fields of application (dotted-border areas)](image)

2. Motivated patients accepting external donning may also use as a definitive splint for daily training. Due to its easy don-doff, fair adjustability and relatively low weight the device may bring benefits to those patients who feel the pressure to take care of their health through daily exercises.

3. Even if health benefits associated with standing and gait exercises declared by 2/3 of respondents could not be objectively confirmed - it is important to provide such an aid for their self-confidence.

4. Due to its relatively low cost and easy distribution the LETOR may become helpful in developing countries too, especially where number of traffic accidents is rising, and the shoes are in use.

5. Since the usefulness of telescopic splint can be checked before the order is placed, consensus yet to be reached that this feature should be regarded as LETOR advantage rather than disadvantage.
Acknowledgement

Designing of the \textit{LETOR} orthosis and its introduction to clinical applications is a result of inspiration -direct or indirect- and/or assistance by specialists and good friends (\textit{listed here in alphabetical order but one}): Marian Weiss, Pawel Baranowski, Hans Bergh, Sławomir Besowski, Bian Wei Guo, Stefan Bieringer, Vinod Bhatti, David Boone, Joanna Bujanowicz, Hector Casanova, Dudley Childress, Joe Chodera, Elizabeth Condie, Marek Darowski, Wiktor Dega, Ed Bieringer, but one-

References

1. Faso D. personal communications 1987-2000
6. Osborne S., Osborne G., Bownes D., Birkett N. Can Repeatability be Improved when Taking Foam Impressions of the Foot? ISPO Hong Kong, FP S1.2 p.347, 2004

\textit{LETOR} is a registered trademark of \textit{Lower Extremity Telescopic Orthosis}